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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CANT(s): CUBERES ALTISEN et al.

SERIAL NO.: 10/804,505 ART UNIT:

FILING DATE: 3/19/04 EXAMINER:

TITLE: SUBSTITUTED AZETIDINE COMPOUNDS, THEIR

PREPARATION AND USE AS MEDICAMENTS

ATTORNEY

DOCKET NO.: 785-011733-US (PAR)

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)(3))

Sir:

This information disclosure statement is being filed before the mailing of a first Office Action on the merits.

The following information is being disclosed to the Patent and Trademark Office as information that may be material to the examination of the above-identified patent application. Applicants' Attorney is aware of the following references:

US 5,073,646

DE 299 21 689 U1

"Health Aspects of Cannabis", Leo E. Hollister

"Chemistry and pharmacology of cannabis", Renu Seth et al.

"Potential Role of Cannabinoids for Therapy of Neurological Disorders", Consroe and Sandyk

- "Novel Syntheses of 1,3,3-Trinitroazetidine", Alan R. Katritzky, et al.
- "Acylative Dealkylation of *N-tert*-Butyl-3-substituted Azetidines: Facile Access to [1.1.0] Azabicyclobutane, 3-Hydroxyazetidinium Hydrochloride, and 3-Azetidinones", Paritosh R. Dave
- "Synthesis of Novel Four-Membered Ring Amino Acids as Modulators of the N-Methyl-D-Aspartate (NMDA) Receptor Complex", Alan P. Kozikowski, et al.
- "Synthesis of 1,3,3-Trinitroazetidine", Theodore Axenron, et al.
- "The selective formation of unsaturated alcohols by hydrogenation of α,β -unsaturated aldehydes in supercritical carbon dioxide using unpromoted Pt/Al₂O₃ catalyst", Bhalchandra M. Bhanage, et al.
 - "Studies on β -Methyl-1-and 3-Phenyl Allyl Chlorides", M.Y. Shandala, et al.
 - "Selective Reduction of Carbonyl Compounds by Polymethylhydrosiloxane in the Presence of Metal Hydride Catalysts", Hubert Mimoun et al.
- "Catalytic Asymmetric Cyclopropanation of Allylic Alcohols with Titanium-TADDOLate: Scope of the Cyclopropanation Reaction", Andre B. Charette, et al.
- "Thionyl Chloride-Benzotriazole in Methylene Chloride: A Convenient Solution for Conversion of Alcohols and Carboxylic Acids Expeditiously into Alkyl Chlorides and Acid Chlorides by Simple Titration", Sachin S. Chaudhari, et al.
- "Activation de la liaison silicium-halogene par les halogenures de bismuth (III). Halogenation des alcohols: perspectives et mecanisme [1]", Mireille Labrouillere, et al.

"Syntheses of Two Cytotoxic Sinapyl Alcohol Derivatives and Isolation of Four New Related Compounds from Ligularia nelumbifolia", Yu Zhao, et al.

"Towards an Understanding of Cram/anti-Cram selectivity on Addition of Crotylboronates to α -Methylbutyraldehyde", Reinhard W. Hoffmann

"Stereospecific Synthesis of 2,3,6-Trisubstituted Piperidines: An Efficient Total Synthesis of (\pm) -Pumiliotoxin C^1 ", Norman A. LeBel, et al.

"Triphenylphosphine/Dichloroselenurane: A New Reagent for a Selective Conversion of Alcohols into Alkyl Chlorides", Jozef Drabowicz, et al.

"Formation of indole nucleus via intramolecular cyclization of aminophenylpropenyltriphenylphosphonium salts with one-carbon degradation", Shin'ichi Taira et al.

"Benzophenone Derivatives and Related Compounds as Potent Histamine H_3 -Receptor Antagonists and Potential PET/SPECT Ligands¹⁾", Astrid Sasse, et al.

"Stereoselective Syntheses of Spicy Components in Peppers",
Akihiro Ohta, et al.

"Negative Inotropic and Calcium Antagonistic Activity of Alkyl and Arylalkyl Phosphonates", Cristina Bellucci, et al.

"Synthesis of 6-(3-Aryl-2-propenyl)-2,3-dihydro-5hydroxybenzofuran Derivatives by Cross Coupling Reactions", Ramon J. Alabaster, et al.

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- dihydro-5-benzofuranol, a Potent Topical Antiinflamatory Agent",
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 - "Configurational Analysis of 1-Alkyl-2-Methylazetidin-3-ols",
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- "New Synthesis of 2-Azetines and 1-Azabutadienes and the Use of the Latter in Diels-Alder Reactions: Total Synthesis of $(\pm)-\delta$ -Coniceine", Michael E. Jung, et al.
 - "Cyclization of 1-Alkylamino-3-halo-2-alkanols to 1-Alkyl-3-azetidinols", V.R. Gaertner
 - "Solid-Phase Synthesis of Oximes", Hajipour, A.R., et al.
- "A Short, Efficient Synthesis of Substituted Uracil: An Indane Carbocyclic Nucleoside", Franco Fernandez, et al.
 - "Benzhydryl and Fluorenyl Lactamimides with Hypoglycemic, Diuretic, Blood Platelet Aggregation Inhibitory, and Antiinflamatory Activities", J. Martin Grisar, et al.
- "Synthesis of Substituted Benzhydrylamines", Yves Dejaegher, et al.
- "7-Azetidinylquinolones as Antibacterial Agents. Synthesis and Structure-Activity Relationships", Jordi Frigola et al.
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 - Properties and Structure-Activity Relationships of Quinolones with an Azetidine Moiety", Jordi Frigola, et al.
- "7-Azetidinylquinolones as Antibacterial Agents. 3. Synthesis,
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- Stereoisomers Containing a 7-(3-Amino-2-methyl-1-azetidinyl)
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- "The First Practical Method for Asymmetric Epoxidation", Ramanuj
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"Progress toward the Total Synthesis of Bafilomycin A_1 : Stereoselective Synthesis of the C15-C25 Subunit by Additions of Nonracemic Allenylzinc Reagents to Aldehydes", James A. Marshall, et al.

- "Amberlyst-15(H⁺)-NaBH₄-LiCl: An Effective Reductor for Oximes and Hydrazones", Bipul Baruah et al.
 - "The Synthesis of Azetidine-3-carboxylic Acid", Arthur G.
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 - "The Azetidines, Recent Synthetic Developments", Norman H.

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 - "Synthese de l'amino-3 azetidine", Dino Nisato, et al.
- "A Short Enantioselective Synthesis of $N\text{-Boc-}\alpha\text{-Amino}$ Acids from Epoxy Alcohols", Marta Poch, et al.
 - "A Versatile Enantiospecific Approach to 3-Azetidinols and Aziridines", Marta Poch, et al.
 - "Synthesis of 1-Alkyl-3-Hydroxy-2-Phenylazetidines", Takashi Toda, et al.
 - "Ring Opening of Azetidinols by Phenols: Regiochemistry and Stereochemistry", Robert H. Higgins, et al.
- "Synthetic Applications of 1-Aminoalkyl Chloromethyl Ketones.

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- "A human whole blood assay for clinical evaluation of biochemical efficacy of cyclooxygenase inhibitors", Brideau et al.
 - "Reactivos Bioquimicos y Organicos para investigation en biociencias" Sigma
- "Basic Section, A new and sensitive method for measuring thermal nociception in cutaneous hyperalgesia", K. Hargreaves, et al.
 - "Carrage Edema in Hind Paw of the Rat as an Assay for Antiinflamatory Drugs", Charles A. Winter, et al.
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- "Effect of nimesulide on cyclo-oxygenase activity in rat gastric mucosa and inflammatory exudate", O. Tofanetti, et al.
- "New Cyclooxygenase-2/5-Lipoxygenase Inhibitors. 1. 7-tert-Butyl-2,3-dihydro-3,3-dimethylbenzofuran Derivatives as Gastrointestinal Safe Antiinflamatory and Analgesic Agents: Discovery and Variation of the 5-Keto Substituent", John M.

 Janusz, et al.
 - 4 pages of Product Information by product number from product catalog (www.caymanchem.com)
 - "Amberlyst-15(H⁺)-NaBH₄-LiG1: An Effective Reductor for Oximes and Hydrazones", Bipul Baruah et al.
- Copies of these references are enclosed together with a Form PTO-1449.

The filing of this Statement is not to be construed as a representation that a search has been made regarding the claimed invention (37 C.F.R. §1.97(g)) or that no other possible material information exists. In addition, the filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,

Geza G. Ziegler

Req. Nb. 44,004

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date indicated below as first class mail in an envelope address to the Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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25 October 2004

Page No.: 1 of: 8

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INFORMATION DISCLOSURE CITATION FORM FOR PATENT APPLICATION (FORM PTO-1449)

Docket No.: 785-011733-US (PAR)

Serial No.: 10/804,505

Applicant(s): CUBERES ALTISEN, et al.

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Page No.: 6 of: 8

Serial No.: 10/804,505 Docket No.: 785-011733-US (PAR) INFORMATION DISCLOSURE CITATION FORM FOR PATENT APPLICATION Applicant(s): CUBERES ALTISEN, et al. (FORM PTO-1449) Group: (Substitute) Filing Date: 3/19/04 U.S. PATENTS **Initials** Patent Number Issue Date Name Class Sub-Filing date class U.S. PATENT PUBLICATIONS Sub-Pub. Date Class Initials Name Filing Date Publication No. class FOREIGN PATENT DOCUMENTS **Initials Document Number** Date Translation? Country Name Yes/No/n/a OTHER DOCUMENTS (Title, Author, Date, Pages, Etc., if known) "The First Practical Method for Asymmetric Epoxidation", Ramanuj Goswami, J. Am. Chem. Soc. 1980, 102, 5974-5976 "Progress toward the Total Synthesis of Bafilomycin A₁: Stereoselective Synthesis of the C15-C25 Subunit by Additions of Nonacemic Allenylzinc Reagents to Aldehydes", James A. Marshall, et al., Organic Letters, 2000, Vol. 2, No. 18 2897-2900 "Amberlyst-15(H⁺)-NaBH₄-LiCl: An Effective Reductor for Oximes and Hydrazones", Bipul Baruah et al., Synlett 1999, No. 4, 409-410 "The Synthesis of Azetidine-3-carboxylic Acid", Arthur G. Anderson, Jr., J. Org. Chem., Vol. 57, No. 24, 1972, 3953-3955 "The Azetidines, Recent Synthetic Developments", Norman H. Cromwell, et al., Chem. Rev., 1979, 79, 331-358 "Synthese de l'amino-3 azetidine" Dino Nisato, et al., J. Heterocyclic Chem. 22, 961-963 (1985) "A Short Enantioselective Synthesis of N-Boc-α-Amino Acids from Epoxy Alcohols", Marta Poch, et al., Tetrahedron Letters, Vol. 34, No. 48, pp. 7781-7784, 1993 "A Versatile Enantiospecific Approach to 3-Azetidinols and Aziridines", Marta Poch, et al., Tetrahedron Letters, Vol. 32, No. 47, pp. 6935-6938, 1991

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Page No.: 7 of: 8

INFORMATION DISCLOSURE **CITATION FORM FOR** PATENT APPLICATION

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Applicant(s): CUBERES ALTISEN, et al.

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Docket No.: 785-011733-US (PAR) Serial No.: 10/804,505 INFORMATION DISCLOSURE CITATION FORM FOR PATENT APPLICATION Applicant(s): CUBERES ALTISEN, et al. (FORM PTO-1449) Group: Filing Date: 3/19/04 (Substitute) U.S. PATENTS Class **Initials** Patent Number Issue Date Name Sub-Filing date class U.S. PATENT PUBLICATIONS Initials Pub. Date Name Class Sub-Filing Date Publication No. class FOREIGN PATENT DOCUMENTS Translation? Initials **Document Number** Date Country Name Yes/No/n/a OTHER DOCUMENTS (Title, Author, Date, Pages, Etc., if known) "Carrage Induced Edema in Hind Paw of the Rat as an Assay for Antiinflamatory Drugs", Charles A. Winter, et al., Proc. Soc. Exp. Biol. Med. 111, 544-547 (1962) "Selective Inhibition of Cyclooxygenase (COX)-2 Reverses Inflammation and Expression of COX-2 and Interleukin 6 in Rat Adjuvant Arthritis", Gary D. Anderson, et al., J. Clin. Invents, Volume 97, Number 11, June 1996, 2672-2679 "Effect of Nimesulide on cyclo-oxygenase activity in rat gastric mucosa and inflammatory exudate", O. Tofanetti, et al., Med. Sci. Res., 1989, 17, 745-746 "New Cyclooxygenase-2/5-Lipoxygenase Inhibitors. 1. 7-tert-Butyl-2,3-dihydro-3,3dimethylbenzofuran Derivatives as Gastrointestinal Safe Antiinflamatory and Analgesic Agents: Discovery and Variation of the 5-Keto Substituent", John M. Janusz, et al., J. Med. Chem, 1998, 41, 1112-1123 4 pages of Product Information by Product Number from www.caymanchem.com product catalog "Amberlyst-15(H⁺)-NaBH₄-LiGI: An Effective Reductor for Oximes and Hydrazones", Bipul Baruah et al., Synlett 1999, No. 4, 409-410 Examiner's Signature: Date Considered:

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